

K 093736

**510 (k) Summary**

MAR 10 2011

(As required by 21 CFR 807.92 and 21 CFR 807.93)

**NAME OF SPONSOR:** DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46582  
Establishment Registration Number: 1818910

**510(K) CONTACT:** Rhonda Myer  
Senior Regulatory Affairs Associate  
Telephone: (574) 371-4927  
Facsimile: (574) 371-4987  
Electronic Mail: [Rmyer7@its.jnj.com](mailto:Rmyer7@its.jnj.com)

**DATE PREPARED:** March 1, 2011

**PROPRIETARY NAME:** DePuy Corail® Hip System, Revision Stem

**COMMON NAME:** Hydroxyapatite-coated hip prosthesis

**CLASSIFICATION:**

- Class III per 21 CFR 888.3330:** Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (KWA)
- Class II per 21 CFR 888.3353:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO)
- Class II per 21 CFR 888.3353:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (MEH)
- Class II per 21 CFR 888.3360:** Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (LWJ)

**DEVICE PRODUCT CODE AND DESCRIPTION:**

- KWA:** prosthesis, hip, semi-constrained (metal uncemented acetabular component)
- LZO:** prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
- MEH:** prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
- LWJ:** prosthesis, hip, semi-constrained, metal/polymer, uncemented

**SUBSTANTIALLY EQUIVALENT DEVICES:** DePuy Corail Hip Stem, K042992  
DePuy KAR™ Hip Stem, K961732

#### **DEVICE DESCRIPTION:**

The Corail Revision Stem is part of a modular prosthesis system for use in total hip replacement. It mates with DePuy femoral heads which articulate with DePuy acetabular systems with either a metal or UHMPE liner. The Corail Hip System, Revision Stem is a line addition to the Corail hip stem family. The stems are available in 9 lengths in sizes 10-20 in standard and high-off versions. The subject titanium alloy hip stems are monolithic, grit blasted stems plasma sprayed with hydroxyapatite powders on the entire stem length. The stems feature a 12/14 AMT (Articul/eze Mini Taper) Taper trunnion which are compatible with previously cleared metal and ceramic DePuy femoral heads with corresponding 12/14 tapers and offsets up to +13 mm.

#### **INDICATIONS AND INTENDED USE:**

##### **Indications:**

The DePuy Corail Revision Stem is indicated for cementless use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia;
2. Avascular necrosis of the femoral head;
3. Acute traumatic fracture of the femoral head or neck;
4. Failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

##### **Intended Use:**

The subject Corail Revision Stem is intended for cementless use as part of the femoral component in a total hip arthroplasty.

##### **Summary of Technologies/Substantial Equivalence:**

The substantial equivalence of the subject Corail Revision Stem is demonstrated by similarities in intended use, indications for use, materials, geometry, design and performance as compared to the predicate devices. The changes presented in this 510(k) do not present new issues of safety or effectiveness as the technological characteristics are basically the same as the predicates. Based on the materials, geometry, mechanical testing and indications for use, the DePuy Corail Revision Hip System is considered to be substantially equivalent to the predicate devices.

##### **Non-clinical Testing:**

Non-clinical testing and analysis were provided, including bench testing and coating characterization. Bench testing included Range of Motion, proximal fatigue, distal fatigue and ceramic head compatibility testing. The nonporous, calcium phosphate coating was applied by plasma spraying to a nominal thickness of  $155 \pm 35$  microns from hydroxyapatite powders. The calcium phosphate coating is applied by a different vendor and was characterized per FDA's "510(k) Information needed for Hydroxyapatite Coated Orthopedic Implants." All of the observed results indicate that the Corail Revision Hip System is substantially equivalent to devices currently marketed. Therefore, the subject device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates.

**Clinical Testing:**

No clinical testing was required to demonstrate substantial equivalence.

**Conclusion:**

The subject Corail Revision Stem is substantially equivalent to the predicate devices identified in this premarket notification.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.  
% Ms. Rhonda Myer  
Senior Regulatory Affairs Associate  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

MAR 10 2011

Re: K093736

Trade/Device Name: DePuy Corail Hip System, Revision Stem

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: Class III

Product Code: KWA, LZO, MEH, LWJ

Dated: February 17, 2011

Received: February 18, 2011

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

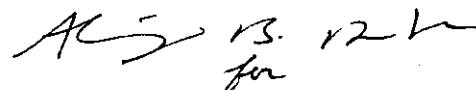
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510 (k) Number (if known): K093736

Device Name: DePuy Corail® Hip System, Revision Stem

### **Indications for Use:**

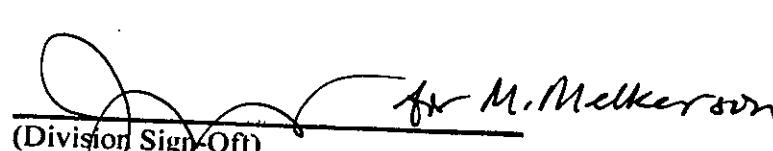
The DePuy Corail Revision Stem is indicated for cementless use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis, or congenital hip dysplasia;
2. Avascular necrosis of the femoral head;
3. Acute traumatic fracture of the femoral head or neck;
4. Failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

---

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K093736